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K031941

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Summary of Safety and Effectiveness
Line Extension to the Hoffmann® II Compact™ External Fixation System – Hoffmann® II Compact™ Baltimore Coupling

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Vivian Kelly Regulatory Affairs Consultant Phone: 201-831-5581 Fax: 201-831-6038
Date of Summary Preparation:	June 20, 2003

Device Identification

Proprietary Name:	Hoffmann® II Compact™ Baltimore Coupling
Common Name:	External Fixation Frame Component
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener, 21 CFR §888.3040

This Special 510(k) submission is intended to address the introduction of a supplemental component to the predicate Hoffmann® II Compact™ External Fixation System. The subject device, named the Hoffmann® II Compact™ Baltimore Coupling, is a line extension of the Hoffmann® II Compact™ Rod to Rod Coupling. The predicate Hoffmann® II Compact™ Rod to Rod Coupling is fabricated from stainless steel and aluminum. The subject Hoffmann® II Compact™ Baltimore Clamp is also fabricated from stainless steel and aluminum. The Hoffmann® II Compact™ Baltimore Coupling is a modification of the Hoffmann® II Compact™ Rod to Rod Coupling. The modification involves a change to the rod to clamp interface which includes a change in profile, an added lip to provide resistance to rod slippage and chamfered edges to aid in rod insertion. Both the predicate Hoffmann® II Compact™ Rod to Rod Coupling and the subject Hoffmann® II Compact™ Baltimore Coupling will be made available to provide surgeons with a choice of couplings for use with the Hoffman® II Compact™ External Fixation System.

The subject Hoffmann® II Compact™ Baltimore Coupling has the same intended use and basic design concepts as the currently available Hoffmann® II Compact™ External Fixation System Rod to Rod Coupling. Mechanical testing demonstrated comparable mechanical properties to the predicate component.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 24 2003

Ms. Vivian Kelly
Regulatory Affairs Consultant
Howmedica Osteonics Corporation
59 Route 17
Allendale, NJ 07401-1677

Re: K031941
Trade/Device Name: Hoffmann® II Compact™ Baltimore Coupling
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: JEC
Dated: June 20, 2003
Received: June 24, 2003

Dear Ms. Kelly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 031941

Device Name: Hoffmann® II Compact™ Baltimore Coupling

Indications For Use:

The Hoffmann® II Compact™ Baltimore Coupling is intended to be used with the components of the Hoffmann® II Compact™ External Fixation System and in conjunction with the half pins or transfixing pins of the Hoffmann® External Fixation System. It is intended to be used in the stabilization of open and/or unstable fractures and where soft tissue injury may preclude the use of other fracture treatments such as IM rodding, casting, or other means of internal fixation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031941